

Environmental Protection Agency

§ 158.2171

life-cycle effects may result from intended use.

20. Since test standards would be developed on a case-by-case basis, consultation with the Agency and development of a protocol is advised before performing these Tier IV studies.

§ 158.2160 Microbial pesticides product performance data requirements.

Product performance data must be developed for all microbial pesticides. However, the Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control public health pests, such as pest microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (including but not limited to: rodents, birds, bats, canids, and skunks) or invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

§ 158.2170 Experimental use permit data requirements—microbial pesticides.

(a) *For all microbial pesticides.* (1) The following § 158.2171 through § 158.2174 identify the data requirements that are required to support experimental use permits for microbial pesticides. The variations in the test conditions are identified within the test notes.

(2) For general information on the data requirement tables, see § 158.2110(a)(2)-(4).

(b) *Additional data requirements for genetically modified microbial pesticides.* Additional requirements for genetically modified microbial pesticides may include but are not limited to: genetic engineering techniques used; the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene); information on the control region of the gene in question; a description of the “new” traits or characteristics that are intended to be expressed; tests to evaluate genetic stability and exchange; and selected Tier II environmental expression and toxicology tests.

§ 158.2171 Experimental use permit microbial pesticides product analysis data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product analysis data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test are identified in (d) of this section, and the test notes appear in paragraph (e) of this section.

(b) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for experimental use permit microbial pesticides product analysis. The test notes are shown in paragraph (d) of this section.

TABLE—EUP MICROBIAL PRODUCT ANALYSIS DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Pat-terns	Test Substance		Test Notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product Identity	R	MP	EP	--
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP	1, 2
	Deposition of a sample in a nationally recognized culture collection	R	TGAI	TGAI	--

TABLE—EUP MICROBIAL PRODUCT ANALYSIS DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
885.1300	Discussion of formation of unintentional ingredients	R	TGAI and MP	TGAI and EP	2
Analysis and Certified Limits					
885.1400	Analysis of samples	R	TGAI and MP	TGAI and EP	2, 3
885.1500	Certification of limits	R	MP	EP	--
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	--
830.6303	Physical state	R	TGAI	TGAI	--
830.6304	Odor	R	TGAI	TGAI	--
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	--
830.6317	Storage stability	R	TGAI and MP	TGAI and EP	--
830.6319	Miscibility	R	MP	EP	4
830.6320	Corrosion Characteristics	R	MP	EP	5
830.7000	pH	R	TGAI	TGAI	--
830.7100	Viscosity	R	MP	EP	6
830.7300	Density/relative density/bulk density (specific gravity)	R	TGAI	TGAI	--

(d) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit microbial pesticides product analysis as referenced in the last column of the table contained in paragraph (c) of this section.

1. If an experimental use permit is being sought, and if the pesticide is not already under full-scale production, a schematic diagram and/or description of the manufacturing process suffices.

2. If an experimental use permit is being sought, and if the product is not already under full-scale production, a discussion of unintentional ingredients is required to be submitted to the extent this information is available.

3. Required to support registration of each manufacturing-use product and end-use product. This analysis must be conducted at the point in the production process after which there would be no potential for microbial contamination or microbial regrowth. For pesticides in the production stage, a preliminary product analytical method and data would suffice to support an experimental use permit. For full registration, generally an analysis of samples is a compilation of

batches, over a period of time, depending on the frequency of manufacturing.

4. Only required for emulsifiable liquid forms of microbial pesticides.

5. Required when microbial pesticides are packaged in metal, plastic, or paper containers.

6. Only required for liquid forms of microbial pesticides.

§ 158.2172 Experimental use permit microbial pesticides residue data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the residue chemistry data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test appear in (d) of this section, and the procedures appear in paragraph (e) of this section.

(b) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All